

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
31 July 2003 (31.07.2003)

PCT

(10) International Publication Number
WO 03/061636 A3

- (51) International Patent Classification⁷: **A61K 9/70**, C12N 15/89, A61M 37/00, A61B 17/20
- (21) International Application Number: PCT/GB03/00282
- (22) International Filing Date: 23 January 2003 (23.01.2003)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
0201736.6 25 January 2002 (25.01.2002) GB
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- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— with international search report
- (88) Date of publication of the international search report:
27 November 2003
- For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: DNA DOSAGE FORMS

(57) Abstract: The present invention relates to efficient devices for administration of DNA based pharmaceutical agents into mammalian skin. In a particularly preferred aspect of the present invention there is provided devices for administration of DNA vaccines into the skin of the mammal, and preferably into human skin. The present invention provides a microneedle DNA pharmaceutical agent delivery device having at least one skin-piercing element which comprises a support member coated with a solid reservoir medium containing, in solid solution or suspension within it, the DNA pharmaceutical agent, and a stabilising agent that inhibits the degradative effects of free radicals. Preferably the solid pharmaceutical reservoir medium coated onto such devices is a polyol, preferably being a polyol in an amorphous state (such as a glass).

INTERNATIONAL SEARCH REPORT

Int. Appl. No.

PCT/GB 03/0282

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K9/70 C12N15/89 A61M37/00 A61B17/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K C12N A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

WPI Data, PAJ, EPO-Internal, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 13277 A (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 9 May 1996 (1996-05-09) page 1, line 16 - line 20 page 31, line 13 - line 14 page 37, line 12 - line 16 page 57 -page 58; example 5 page 75; claim 19	1-27
A	WO 97 40839 A (MERCK & CO., INC.) 6 November 1997 (1997-11-06) cited in the application claims 1-43	1-27
A	EP 1 138 337 A (QUADRANT HOLDINGS CAMBRIDGE) 4 October 2001 (2001-10-04) claims 1-3,20,27,28	1-27



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

15 August 2003

Date of mailing of the international search report

26/08/2003

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INTERNATIONAL SEARCH REPORT

Int. Application No
PCT/GB 00282

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9613277	A	09-05-1996	US 5804566 A	08-09-1998
			AU 698826 B2	05-11-1998
			AU 4199496 A	23-05-1996
			CA 2204253 A1	09-05-1996
			EP 0794797 A1	17-09-1997
			JP 10509438 T	14-09-1998
			WO 9613277 A1	09-05-1996
			US 2003027782 A1	06-02-2003
			US 5849719 A	15-12-1998
WO 9740839	A	06-11-1997	AU 727306 B2	07-12-2000
			AU 2924297 A	19-11-1997
			CA 2252565 A1	06-11-1997
			EP 0906110 A1	07-04-1999
			JP 2002504085 T	05-02-2002
			WO 9740839 A1	06-11-1997
			US 2002156037 A1	24-10-2002
			ZA 9703642 A	25-11-1997
EP 1138337	A	04-10-2001	US 6290991 B1	18-09-2001
			EP 1138319 A2	04-10-2001
			EP 1138337 A2	04-10-2001
			AU 688557 B2	12-03-1998
			AU 3185195 A	04-03-1996
			AU 707605 B2	15-07-1999
			AU 7186498 A	20-08-1998
			BG 101278 A	30-12-1997
			CA 2197982 A1	15-02-1996
			CZ 9700476 A3	13-08-1997
			EE 9700062 A	15-08-1997
			EP 0773781 A1	21-05-1997
			FI 970867 A	08-04-1997
			WO 9603978 A1	15-02-1996
			HU 77777 A2	28-08-1998
			JP 10503769 T	07-04-1998
			NO 971688 A	11-04-1997
			NZ 290896 A	24-04-1997
			PL 318898 A1	21-07-1997
			RU 2177785 C2	10-01-2002
			SK 27797 A3	06-08-1997
			US 2001038858 A1	08-11-2001
			US 2003054040 A1	20-03-2003
			US 6331310 B1	18-12-2001
			US 2002012687 A1	31-01-2002